POISON PILL: IMPORTING FOREIGN DRUG PRICE CONTROLS

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INTRODUCTION
The price of prescription medication in the United States is oftentimes exorbitantly high, and Americans incur greater costs on healthcare than the citizens of most other countries. To combat this, the Department of Health and Human Services (HHS) proposed tying drug reimbursements under Medicare Part B to the prices in a host of foreign nations. A legislative version of this proposal has been introduced in Congress, which would apply to the entire healthcare system.

While attempting to strike at the heart of a very serious, very real issue for Americans, one proposal clearly violates the law while both violate the laws of economics. It is important to highlight those economic problems, as well as the relevant statutes surrounding the HHS proposal to ensure that future proposals avoid such issues.

ABSTRACT
Both the regulatory and legislative proposals to index domestic drug prices to foreign prices run into the same serious economic issues. However one serious flaw trumps all others. The focus of the paper is on the fact that governments cannot effectively set efficient prices. The effort to do so ignores the purpose of prices in the first place. Prices convey critical information about supply and demand. The problem with America’s healthcare system is that government has progressively obscured the pricing system. No proposal that does not address this fundamental fact stands a chance of turning back runaway healthcare price inflation.

In addition, the regulatory proposal is likely illegal, as the Center for Medicare and Medicaid Innovation is only authorized to conduct limited experiments to improve care in the United States. The proposed international price index (IPI) would apply to roughly half of the country and many Medicare Part B drugs. This is hardly a limited experiment. Congress has also prohibited using Medicare as a price-fixing tool. The regulatory approach amounts to massive overreach.
BACKGROUND
The healthcare system in the United States is facing an undeniable economic crisis. While Americans enjoy the best healthcare in the world in most respects, the cost of healthcare is unsustainable and rising. There is no disagreement on this simple fact.

Medical price inflation is now roughly double that of overall price inflation, and accelerating:

MEDICAL CARE INFLATION vs. TOTAL INFLATION (1947-2018)¹

This poses an immediate problem for the Medicare program and the federal budget as a whole.

Medicare is a federal government program that covers most of the cost of healthcare for Americans over the age of 65 and some Americans younger than 65 who are permanently disabled.

Medicare has four parts: Part A, Part B, Part C, and Part D. The Congressional Research Service defines each part as follows:

Part A: Part A provides coverage for inpatient hospital services, post-hospital skilled nursing facility services, hospice care, and some home health services, subject to certain conditions and limitations.

Part B: Medicare Part B covers physicians’ services, outpatient hospital services, durable medical equipment, and other medical services.

Part C, or Medicare Advantage: Medicare Advantage (MA) is an alternative way for Medicare beneficiaries to receive covered benefits. Under MA, private health plans are paid a per-person amount to provide all Medicare covered benefits (except hospice) to beneficiaries who enroll in their plan.

Part D: Medicare Part D provides coverage of outpatient prescription drugs to Medicare beneficiaries who choose to enroll in this optional benefit.²

Medicare is funded primarily through taxes on current workers, paying for current retirees and other beneficiaries.³ In 2018, the federal government spent a total of $4.108 trillion dollars. Of this, Medicare comprised $704.3 billion, or roughly 17 percent of total federal spending. This makes Medicare currently the second-largest single budget expenditures of the federal government, behind Social Security, which spent $982.2 billion, and ahead of defense spending, which totaled $621.7 billion.⁴

While currently the second largest source of spending, Medicare presents the most significant budget issue for the federal government in the near and long terms. Under current law, both Social Security and Medicare are slated to owe

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³ ibid.
far more to future beneficiaries than the programs will take in through current
dedicated revenue sources. These shortfalls are called unfunded liabilities. The
most recent unfunded liability estimate for Social Security over the next 75
years is $13.2 trillion. However, the most recent unfunded liability estimate for
Medicare is $37.7 trillion over 75 years.

Most of the unfunded liability from Medicare is derived from the fact that
Medicare Part B funding is reliant on general revenues to the federal
government. In other words, Medicare Part B lacks sufficient dedicated
funding sources, such as patient premiums and Medicare-specific payroll
taxes, to cover all of its expenses and must draw on funds collected by
income taxes, corporate taxes, borrowing, etc. The amount of federal general
revenue funding Part B will require over the next 75 years is $25.1 trillion.

Every dollar Congress is obligated to spend supplementing Medicare Part B is
a dollar that cannot be spent on other priorities, from defense to other social
programs. Thus, it should come as no surprise that policymakers on both sides
of the aisle have floated proposals to reduce the financial burden of Medicare
Part B. What is surprising, however, is that a regulatory proposal from the
Trump administration’s Department of Health and Human Services (HHS) is
functionally the same as a bill introduced by Sen. Bernie Sanders (I-Vt.) and
Rep. Ro Khanna (D-Calif.).

The HHS regulatory proposal focuses on drug reimbursements under
Medicare Part B. With some significant exceptions, drugs covered under
Medicare Part B are the medicines that are administered by healthcare
providers while patients are in their care. The legislative proposal
encompasses the entire prescription drug industry. Despite these differences,
the proposals all look to use a formula based on drug prices in certain foreign
countries as a basis for drug prices in the United States. The HHS regulatory

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5 2018 Annual Report of the Board of Trustees for the Federal Old-Age and Survivors
Insurance and Federal Disability Insurance Trust Funds.
7 Ibid.
8 Ibid.
9 Davis et al.
proposal refers to this as an “International Price Index”\textsuperscript{10} (IPI) while the legislation creates an “International Reference Price.”\textsuperscript{11}

The HHS proposal suggests basing prices off of the following nations: Austria, Belgium, Canada, Czech Republic, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Japan, Netherlands, and the United Kingdom.

The legislative version specifically lists Canada, the United Kingdom, Germany, France, and Japan.

At a minimum, each of these countries impose some sort of price regulation on pharmaceuticals, either through price controls or through the fact that the government is practically the sole insurer and/or provider of healthcare services in the nation.\textsuperscript{12}

The central idea of both the regulatory and legislative proposals is that foreign governments with far more active roles in their nations’ healthcare systems, to the point that some are almost entirely funded and operated by the government, have been able to secure prices lower than what is being charged for the same drugs in America. In turn, by forcing drug companies to accept a price based on prices imposed by other nations, Americans will receive the same treatment at a lower cost but drug manufacturers will still receive acceptable compensation.

While Americans generally value bipartisan agreement, the central idea of this consensus rests upon fundamentally flawed economics. In addition, the Trump administration’s version of this proposal raises serious constitutional issues.

\textsuperscript{12} Vogler, Sabine & Martikainen, Jaana. (2014). Pharmaceutical Pricing in Europe. 10.1007/978-3-319-12169-7_19.
REGULATORY OVERREACH

“In a republic, it is not too much to expect that law will be made by a legislature composed of representatives of the people. It is, in fact, the very nature of a republic to be governed by laws made by this sort of specialized legislative body.

“Nonetheless, administrative legislation is unrepresentative. It therefore is without consent, without obligation, and without popular accountability. Indeed, it is form of class power, without a regular means aligning itself to popular sentiment. None of this bodes well, but it is exactly what might be expected when a people no longer merely govern themselves, but are forced to comply with the commands of unelected administrators.”—Philip Hamburger, Is Administrative Law Unlawful?13

Before discussing the economic problems common to the regulatory and legislative proposals to index domestic drug prices to foreign prices, there are significant legal issues unique to the HHS IPI regulatory proposal.

The HHS proposal would actually be a project of the Center for Medicare and Medicaid Innovation (CMMI), itself within HHS’s Center for Medicare and Medicaid Services. CMMI was created by the Patient Protection and Affordable Care Act, better known as Obamacare.14

While the statute itself is broad, it clearly states that CMMI is to conduct limited experiments within Medicare and Medicaid to improve the programs in terms of reducing expenditures and/or improving health outcomes. The statute explicitly instructs CMMI to test experimental models on a “defined population.”15

The IPI regulatory proposal goes well beyond a limited experiment on a “defined population.” HHS readily admits that this proposal will apply to “50 percent of the country, and would cover most of the drugs in Medicare Part

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15 42 U.S. Code §1315 a. Center for Medicare and Medicaid Innovation
B. This clearly exceeds the bounds of the law and the intent of Congress for CMMI to conduct limited experiments. Imposing a new payment model on half of the country as well as many of the drugs in a certain category can in no way be considered a limited experiment. What is actually happening is an attempt to impose wholesale change to the structure of Medicare through unilateral executive action—a backdoor to imposing price controls across the entire healthcare system.

Imposing a new pricing system based on international price controls on half of Medicare Part B would have spillover effects on the other half and beyond. Currently, Medicare Part B reimburses the cost of drugs based on the metric of Average Sales Price (ASP). ASP “is a manufacturer’s average price to all purchasers, net of discounts, rebates, chargebacks, and credits for drugs. ASP is determined using manufacturers’ sales reports, which include information on total units sold and total revenue for each drug, and is subject to audit by Medicare.” ASP was implemented by Congress through the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 as a way to capture significant discounts and rebates private purchasers of medicine often receive from drug makers.

By HHS’s own admission, implementing the proposed IPI would result in ASP reductions for those outside the experimental model. In remarks delivered at the Brookings Institution, HHS Secretary Alex Azar stated, “It’s not just patients in areas covered by the model who can benefit, however. As payments within the model are reduced, the average sales price Medicare pays will drop, reducing what patients outside the model pay.”

Secretary Azar was not just referring to patients within Medicare outside of the model, but indeed the entire country. Howard Deutsch and Gustavo Poblete of ZS Associates offer a clear explanation:

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18 Ibid.

“The government envisions that to meet the reduced ‘target prices’ that Medicare will pay in the pilot, manufacturers will discount their drugs down to that level. Those discounts will, in turn, reduce drug ASP elsewhere and will consequently reduce the amount that Medicare (and many commercial health plans) reimburse outside of the pilot to providers that continue to buy and bill. At the price reduction levels targeted by the government, this will make business as usual impossible.

“Let’s consider this simple example: Providers who purchase a drug under the current model with an ASP of $1,000 per dose and 50% of its utilization in Medicare are being reimbursed $1,043. If Medicare realizes its targeted 30% price reduction in the pilot geographies, the ASP will reset to $925 over time. At that point, the non-pilot provider who purchases at $1,000 will only be reimbursed $965, which isn’t economically viable.”

Congress never intended HHS to set prices through Medicare, indeed explicitly barring HHS from engaging in direct price negotiations and fixing. As discussed below, the government is ineffective at determining optimal price levels for any product and generally should not be involved in price negotiations due to its power to impose coercive transactions versus voluntary exchanges. This is why the current ASP structure forces Medicare to base its drug reimbursement on prices reached between private actors, such as insurance companies or providers and the drug companies themselves.

A similar, but far more limited CMMI experimental proposal to put pressure on pharmaceutical prices through Medicare was shelved in 2016 after complaints that it significantly exceeded the scope of the law. The proposal included adopting “value-based purchasing tools like those used by commercial health plans, pharmacy benefit managers, hospitals and others that manage health

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21 “The Politics of Medicare and Drug-Price Negotiation (Updated),” Health Affairs Blog, September 19, 2016. DOI: 10.1377/hblog20160919.056632
benefits and drug utilization.” In short, Medicare would have played an active role in pricing as opposed to basing its reimbursements on prices reached in the private marketplace.

In summary, not only is the current HHS IPI proposal a massive overreach of the authority granted to CMMI, it is a direct breach of the explicit intent of Congress when it barred Medicare from negotiating or price fixing in the drug market.

**ECONOMIC ISSUES**

“It is the very essence of prices that they are the offshoot of the actions of individuals and groups of individuals acting on their own behalf. The catallactic concept of exchange ratios and prices precludes anything that is the effect of actions of a central authority, of people resorting to violence and threats in the name of society or the state or of an armed pressure group. In declaring that it is not the business of the government to determine prices, we do not step beyond the borders of logical thinking. A government can no more determine prices than a goose can lay hen’s eggs.” – Ludwig Von Mises, *Human Action*²³

In discussing the economics of these proposals, IPI will refer to both the regulatory International Price Index and the legislative International Reference Price, as they both present the same economic problems.

Understanding the fundamental flaws with the IPI requires understanding the definition and role of prices for any good or service. Prices are signals. These signals convey information about how individuals in a market value different things. These signals help individual actors in the market allocate scarce resources towards more valuable or efficient uses. Most are likely familiar with the concepts of supply and demand. Prices help move supply and demand towards an efficient equilibrium in a free market.

However, prices can become distorted by government. Various policies can alter the signals producers and consumers receive. At this point the signals

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cease to be prices in the same way that a newspaper reporting nonsense becomes a tabloid. Actors in the market believe they are reading correct prices and act accordingly, but the market is no longer moving towards equilibrium. If policy causes the signals to be artificially high, producers waste resources creating things people do not actually value at that level, generating inefficiencies in other areas of the market where those resources could be put to more valuable use. More germane to the issue of the IPI is what happens when policy causes the signals to be artificially low.

As Henry Hazlitt describes in his classic book, *Economics in One Lesson*:

“[W]e cannot hold the price of any commodity below its market level without in time bringing about two consequences. The first is to increase the demand for that commodity. Because the commodity is cheaper, people are both tempted to buy, and can afford to buy, more of it. The second consequence is to reduce the supply of that commodity. Because people buy more, the accumulated supply is more quickly taken from the shelves of merchants. But in addition to this, production of that commodity is discouraged.”

The core problem with America’s healthcare system is the lack of a functional price system as a result of progressively increasing government interventions. Practically since the dawn of modern medicine itself, the federal government has limited the role of direct price signals between consumers and producers of healthcare. Beginning in 1943, the federal government began officially subsidizing employer-sponsored health insurance. Ironically enough, employers began providing health insurance as a way to avoid government price controls imposed on wages.

Since employers can increase their employees’ total overall compensation without incurring a tax penalty by offering health insurance, employers naturally began to compete for labor by offering more and more comprehensive health insurance plans. With more and more treatments covered, insurance soon became the dominant way to pay for healthcare.

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Since insurance was tied to compensation for employment, retired and indigent Americans were naturally left behind. In 1965, the federal government created Medicare and Medicaid, effectively turning the federal government into the insurance company for elderly and poor Americans.

These programs have gradually been expanded in the years since in terms of both eligibility and coverage. In 2003, Medicare Part D was created to cover the cost of prescription drugs. In 2010, the Patient Protection and Affordable Care Act, better known as Obamacare, significantly expanded Medicaid coverage.

In addition, Obamacare also made massive changes to the private insurance system as well. It not only mandated all Americans have some form of insurance coverage, it set minimum standards of acceptable insurance coverage, further increasing the role of third parties and diminishing the role of direct prices for more patients and treatments.

The result of all these government interventions in the American healthcare system is that the flow of information usually conducted passively through a price system does not exist between consumers and producers of healthcare: patients and medical providers such as drug companies, doctors, and hospitals. Without the flow of the critical information about supply and demand through prices, the market does not trend towards an efficient equilibrium. An inefficient healthcare market is naturally more expensive.

The entire point of insurance is that, at some level, the marginal cost to the patient is zero. What this means is that, depending on the specifics of the patient’s coverage, at some point their next treatment will not cost them anything more regardless of whether it is a simple drug treatment or a complicated surgery. This has a number of effects on behavior. Patients are not concerned with how much one provider charges versus another and thus providers rarely compete to offer the best service at the lowest price. In fact, they often compete by providing more expensive and superfluous services to attract patients. In addition, patients over-consume healthcare which leads to scarcity. In short, the level of demand in healthcare becomes untethered and prices respond accordingly by rising to attract new production and providers to meet the excessive demand and combat scarcity.
Rising prices for healthcare is thus caused primarily by insurance systems, private and government. As insurance has become the primary way to pay for healthcare, paying for certain healthcare services without insurance has become prohibitive to most Americans. The only reason that a healthcare provider has to charge someone paying without insurance less is the time and other resources the provider will save when it comes to dealing with the insurance company or government agency in seeking reimbursement. Otherwise, the same resources being used to provide treatment to a patient paying with cash could be used on an insured patient. With booming demand, the resources are going to flow to where they generate the greatest returns for the providers, leaving those without insurance facing astronomical costs for healthcare.

Unfortunately, the government’s response to this problem has always been focused on further shielding patients from excessive prices by expanding insurance benefits and government coverage, not utilizing the power of patients to actually drive prices down. What this means is that Medicare is not just crumbling under medical price inflation, it is a significant cause of it as well. So long as healthcare policy continues to promote the usage of third-party payers, such as insurance companies and Medicare, the healthcare marketplace will always feature significant inefficiencies, and thus be more expensive.

The IPI is fundamentally flawed because it does nothing to address the root cause of healthcare price inflation: the third-party payer-dominant model. The IPI would only change the nature of the harmful outcomes caused by the inefficiencies.

In third-party payer systems, be they single-payer systems of the kind which the IPI would partially-base prices or private insurance systems, demand is not sufficiently responsive to prices. There are only two outcomes when this happens. Prices either continue to rise and the third-parties continue to increase either insurance premiums or the level of taxation, or the third-parties begin constraining costs ultimately leading to shortages and a lack of innovation.

The IPI is a cost-constraint mechanism. By setting prices at a level below what drug companies would otherwise charge in a free and mutually-beneficial exchange with a customer, the IPI would significantly reduce the incentive for
companies to produce existing drugs, leading to shortages as patients’ demand continues to increase. Drug companies would also see their incentive to invest in developing new treatments severely undercut. In this sense, there would be a shortage in terms of the level of innovation in the market. Both ultimately leave patients worse off in terms of health outcomes.

The economic reality of price controls causing shortages is implicit in the structure of the IPI. The entire point of basing the price controls off of prices imposed in other countries is the deeply-flawed perception that these other nations have imposed price controls on medicine and don’t seem to be suffering the kinds of drastic consequences one would expect. The problem with this argument is that the problem the IPI seeks to remedy, higher drug prices in America, is in-part a product of price controls imposed in other countries.

While there are a number of factors putting upward pressure on drug prices in America, one of them is the fact that international price controls force drug companies to recoup their investments in research and development where they are not subject to price controls. The IPI is thus nothing more than an attempt to free-ride on top of a massive free-rider problem.

The evidence that the United States leads the world in pharmaceutical research and development is overwhelming. In 2015, spending on drug research and development in the United States totaled an estimated $47.1 billion versus $37.3 billion in Europe. From 2002 through 2016, the average growth rate in pharmaceutical research and development spending in the United States was 5.43 percent compared to 4.23 percent in Europe. American pharmaceutical companies have also consistently led the world in discovery of new chemical and biological entities with 304 between 1997 and 2016, compared to 252 for European companies, 102 for Japanese firms, and 68 for the rest of the world combined.

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27 The Pharmaceutical Industry in Figures

Regardless of where the research and development is occurring, it must be funded. America leads the way here as well. According to a recent study published by the Schaeffer Center for Health Policy & Economics at the University of Southern California, “U.S. consumers account for about 64 to 78 percent of total pharmaceutical profits, despite accounting for only 27 percent of global income.”\(^\text{29}\) That study goes on to offer an important anecdote about the obviousness of the foreign free-rider problem:

“In April 2017, the Schaeffer Center hosted a panel discussion featuring Sir Michael Rawlins, Chair of the UK’s Medicine and Healthcare Products Regulatory Agency — Britain’s equivalent of the FDA — who emphasized the global importance of continuing pharmaceutical innovation. Recognizing the costs of developing new drugs, he said, ‘you are talking about a lot of money. And thank you very much to the United States’ for shouldering that burden.’\(^\text{30}\)

While foreign countries do free-ride on America in terms of medical innovation, the negative impacts of price controls are still visible in those nations. Americans consistently have much greater access to new medicines. The United States accounted for 64.7 percent of sales of all new medicines introduced between 2011 and 2016, compared to 17.5 percent combined in Italy, France, the United Kingdom, Spain, and Germany, and 7.3 percent in Japan.\(^\text{31}\) Drugs that save American lives simply aren’t available in countries that impose price controls. For example, 95 percent of new cancer treatment drugs launched globally are available in the United States, whereas only 74 percent are available in the United Kingdom, 49 percent in Japan, and just 8 percent in Greece.\(^\text{32}\)

The evidence clearly demonstrates that medicine is not immune to basic economics. Price controls, specifically price ceilings, lead to shortages and diminished investment and innovation.


\(^{30}\) Ibid.

\(^{31}\) The Pharmaceutical Industry in Figures

Yet it is true that some medicines are readily available in foreign countries at much lower prices than they are in the United States. This naturally raises the question as to why pharmaceutical companies are willing to accept price controls in these nations.

The answer to this question is also an answer to why the power of the government to negotiate prices should be limited and why Medicare reimbursements currently reflect prices that are found in transactions between private actors. Governments hold a monopoly on coercive power within their jurisdictions. The checks against this vary wildly from nation to nation. Negotiating prices with a government is not the same as negotiating prices with another private actor in the market. Governments hold the unique ability to apply coercive pressure on firms in order to induce a transaction which would otherwise not occur.

Exchanges in a free market occur voluntarily because both sides feel they will be better off, which ultimately generates value and grows the economy. When dealing with a government, a company may agree to terms it otherwise would not in order to either secure a special privilege from the government or avoid punitive actions such as new taxes, regulations, or investigations. These kinds of coerced transactions produce prices that are not accurate indicators of the value of the goods or services that are ultimately exchanged, leading to economic inefficiency and stifled economic growth.

So long as companies that produce pharmaceuticals seek to do business in these countries, even selling non-prescription products or non-pharmaceutical products, they are captive to the respective governments. Citizens of those countries may enjoy lower prices on certain medications, but it comes at the astronomical cost of reduced access to medicine and lower local research and development investment.

The IPI presents several other peripheral economic issues as well. There are problems related to differences in personal income in the United States versus foreign countries, issues with international currency exchange rates impacting prices, intellectual-property arguments, and countless other issues relating to disparate socio-economic, trade, and regulatory policies from nation to nation. All ultimately have an impact on prices for medicine.
However, the IPI is flawed at such a fundamental level that discussing some of these peripheral issues at any length gives undue credence to the idea that foreign governments are able to set efficient prices. No government is capable of setting efficient prices for anything. Adopting an index of these prices would not only subject Americans to the same dearth of new medicines and pharmaceutical research and development that plagues the rest of the world, but would also severely weaken the world’s main engine for pharmaceutical research and development.

CONCLUSION
It is imperative that rising healthcare prices in the United States be addressed by policymakers. However, imposing cost constraints on the producers of healthcare, such as pharmaceutical companies, suppresses a symptom without curing the problem while causing major side-effects. Imposing price controls may lead to lower costs, but Americans will get what they’re paying for in terms of lower quality healthcare, reduced investment in new treatments, and drug shortages brought on by overconsumption.

Governments do not have the ability to set prices without imposing inefficiencies on the market. Price ceilings such as the IPI necessarily result in excess demand and insufficient supply, as demonstrated by the lack of investment in research and development and access to new medicines in the countries upon which the IPI would be based. This chilling effect on innovation caused by price controls is why HHS is barred by law from imposing them or attempting to deliberately use Medicare to influence prices in the private marketplace. This protection should be executed faithfully by HHS, not subverted.

The only way to sustainably address the problem of healthcare price inflation is to reduce the role of the government intervention that distorts the market – impacting prices and the balance of supply and demand – and allow patients to understand the true cost of their care. The third-party dominant model of subsidized insurance and government insurance programs covering most all healthcare costs only subsidizes excess demand. Without addressing the demand side of the market, cost constraints like the IPI only serve to make healthcare systems slightly more affordable while infinitely less effective at providing care and producing new treatments.

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